

construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of Groups I and II above are independent. Rather, the Examiner alleges that the inventions of Groups I and II are distinct because the product as claimed can be used in a materially different process, such as such as any one of the known insulin therapies (Office Action at page 2). In addition, the Examiner alleges that the inventions of Groups I and III are distinct because invention II has a separate utility such as any one of the well known composition preparation techniques such as mixing, combining etc. (Office Action at page 2). Applicants assert that restriction between these dependent inventions is improper.

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion had been met in the present case, which it has not, the second criterion has not been met.

The Examiner asserts that restriction is proper because the inventions have acquired a separate status in the art due to their recognized divergent subject matter and due to their different classifications (Office Action at page 2). Even if restriction is supported by a showing of separate classifications, such a *prima facie* showing by the Examiner of a serious burden due to the separate classification of the 3 groups of the invention is rebuttable (M.P.E.P. §803).

Applicants assert that a search into prior art with regard to the invention of Groups I-III is so related that separate significant search efforts should not be necessary. Accordingly, there is no serious burden on the Examiner to collectively examine Groups I-III of the subject application. Therefore, restriction is not proper under M.P.E.P. §803.

## II. ELECTION OF SPECIES

The Office Action dated November 11, 2000 required the election of a single disclosed species of the invention from the species that the Examiner designates A (each agent i, ii and iii), B (insulin sensitizer) and C (surfactants) (Office Action at page 3). In response to this requirement, Applicants elect species A with traverse. Claims readable on species A are claims 1-25 and 59-71.

### III. CONCLUSION

For the reasons noted above, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement as well as the requirement to elect a single species. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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By their attorneys,

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